

Nuclear Regulatory Commission

§ 35.315

§ 35.220 Possession of survey instruments.

A licensee authorized to use byproduct material for imaging and localization studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart F—Radiopharmaceuticals for Therapy

§ 35.300 Use of unsealed byproduct material for therapeutic administration.

A licensee may use for therapeutic administration any unsealed byproduct material prepared for medical use that is either:

- (a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or
- (b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 35.920, or an individual under the supervision of either as specified in § 35.25.

[59 FR 61784, Dec. 2, 1994]

§ 35.310 Safety instruction.

(a) A licensee shall provide radiation safety instruction for all personnel caring for the patient or the human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter. To satisfy this requirement, the instruction must describe the licensee's procedures for:

- (1) Patient or human research subject control;
- (2) Visitor control;
- (3) Contamination control;
- (4) Waste control; and
- (5) Notification of the Radiation Safety Officer in case of the patient's or the human research subject's death or medical emergency.

(b) A licensee shall keep for three years a list of individuals receiving instruction required by paragraph (a) of

this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 59 FR 61784, Dec. 2, 1994]

§ 35.315 Safety precautions.

(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter, a licensee shall:

(1) Provide a private room with a private sanitary facility;

(2) Post the patient's or the human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;

(3) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of part 20 of this chapter, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(5) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.

(6) [Reserved]

(7) Survey the patient's or the human research subject's room and private sanitary facility for removable contamination with a radiation detection

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survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and

(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by §20.1206(a) of this chapter a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 59 FR 61784, Dec. 2, 1994; 62 FR 4133, Jan. 29, 1997]

§ 35.320 Possession of survey instruments.

A licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart G—Sources for Brachytherapy

§ 35.400 Use of sources for brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

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(c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(d) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(e) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

(f) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer.

(g) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

[51 FR 36951, Oct. 16, 1986, as amended at 54 FR 41821, Oct. 12, 1989]

§ 35.404 Release of patients or human research subjects treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of patient or human research subject surveys for three years. Each record must include the date of the survey, the name of the patient or the human research subject, the dose rate from the patient or the human research subject expressed as millirem per hour and measured at 1 meter from the patient or the human research subject, the survey instrument used, and the initials of the individual who made the survey.

[59 FR 61785, Dec. 2, 1994]

§ 35.406 Brachytherapy sources inventory.

(a) Promptly after removing them from a patient or a human research subject, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.